UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	
	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:	)	
All Cases	)	

NOTICE OF SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS

Please take notice that the Custodian of Records for Brigham and Women's Hospital has been issued a subpoena to produce documents, information, or objects for deposition on the 7th day of May, 2015, at 10:00 a.m., at Ellis & Rapacki LLP, 85 Merrimac Street, Suite 500, Boston, MA 02114, identified on Exhibit A to the attached subpoena.

Dated: April 6, 2015

Respectfully submitted,

/s/ Kristen Johnson
Thomas Sobol, Esq. BBO#471770
Kristen Johnson, Esq. BBO#667261
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LEAD COUNSEL FOR PLAINTIFFS STEERING COMMITTEE

CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2015, a true copy of the foregoing was filed in accordance with the Court's Electronic Filing Guidelines and will be sent to all counsel of record by operation of the Court's electronic filing system.

/s/ Kristen Johnson
Kristen Johnson, Esq.

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation

Plaintiff

v.

Defendant

Civil Action No. 1:13-md-02419

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Keeper of the Records, Brigham and Women's Hospital

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Exhibit A.

Place:	Date and Time:
Ellis & Rapacki LLP 85 Merrimac Street, Suite 500 Boston, MA 02114	05/07/2015 10:00 am

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 04/06/2015

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* The Plaintiffs Steering Committee, who issues or requests this subpoena, are:

Fredric L. Ellis, Ellis & Rapacki LLP, 85 Merrimac St, Ste 500, Boston, MA 02114, rellis@ellisrapacki.com, 617-523-4800

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

EXHIBIT A

Exhibit A

1. All documents and electronically stored information referring to or concerning the USP <797> compliance program ("Compliance Program") utilized by the Brigham and Women's Hospital's pharmacy services department (the "pharmacy services department") during the calendar years 2010 through 2012 (the "Relevant Years"), including without limitation all documents referring to or concerning:

a. All standard operating procedures (SOPs) for gowning, cleaning and environmental monitoring applicable at any time during the Relevant Years;
b. The results of all environmental monitoring testing performed during the Relevant Years;
c. All documents concerning or referring to USP <71> sterility testing at any time during the Relevant Years, including testing requirements, SOPs, sterility test results, and validation testing results;
d. The "formal quality standard operating procedures" for the compounding of sterile preparations (CSPs), as referenced in the article entitled, "A first hand look at successful USP 797 compliance," published February 1, 2007 in Solid State Technology, a copy of which is attached as Addendum 1 hereto and incorporated herein by reference;
e. All USP <797> compliance education, training, and testing materials provided to, or made available to, CSP staff during the Relevant Years;
f. All SOPs applicable to the pharmacy services department and/or its outside vendors, including vendors providing sterility testing, cleanroom cleaning and sanitization services, at any time during the Relevant Years;
g. All audits and/or inspections of the pharmacy services department at any time during the Relevant Years, including the results of all audits presented by the Director of Pharmacy Compliance, Quality, and Safety.

2. All documents and electronically stored information referring to or concerning Brigham and Women's 2008 audit of New England Compounding Pharmacy ("NECP").

3. All documents and electronically stored information referring to or concerning any sterility and/or endotoxin testing conducted on NECP's products during the Relevant Years.

4. All documents and electronically stored information referring to or concerning the draft agenda for the May 4, 2012 vendor audit of NECP, as sent by Michael Cotugno to Barry Cadden by e-mail on May 3, 2012.

5. All documents and electronically stored information supplied by NECP in connection with the May 4, 2012 vendor audit of NECP, including the pdf attachment to the e-mail sent by Barry Cadden to Michael Cotugno on May 4, 2012 at approximately 2:43 p.m.

6. All documents and electronically stored information referring to or concerning any changes made to Brigham and Women's Standard Operating Procedures for Qualification of Outside Vendors (Vendor Audit Policy) or the vendor audit form used by Brigham and Women's to conduct vendor audits since September 26, 2012.

ADDENDUM 1

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ISSUE

A firsthand look at successful USP 797 compliance

02/01/2007

Implementation of a compliance program improves pharmacy compounding quality at a major Boston hospital

By Fran McAteer, Microbiology Research Associates; William Churchill, John Fanikos, Michael Cotugno, and Caryn Domenici, Brigham and Women's Hospital

The pharmacy services department of Brigham and Women's Hospital (BWH), a major urban hospital in Boston, MA, has initiated a comprehensive USP <797> compliance program, the experiences of which stand to greatly benefit many other hospital pharmacy facilities and managers.

The BWH project began with the development of a detailed project management plan, called a GAP analysis, detailing myriad compliance issues and resulting in the decision by senior management to pursue a proactive strategy for USP <797> implementation. The project set out multiple phases and included a nonbiased expert audit of the hospital's existing operation. This audit included:

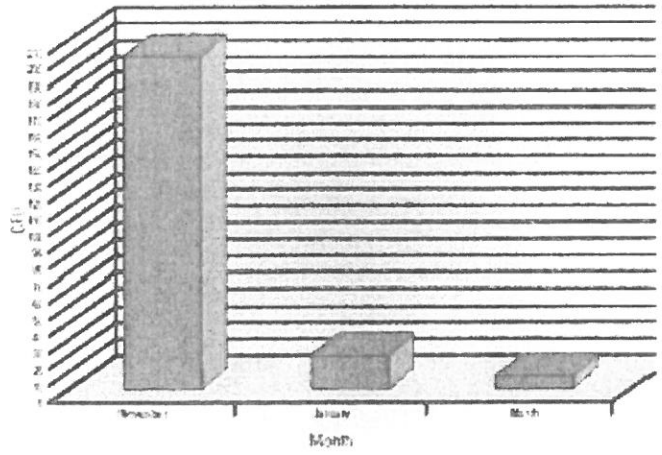
a comprehensive review of quality documentation
interviewing compounding personnel
testing for viable particles
observing aseptic processing
monitoring the cleanroom environment
assessing the facility design
inspecting training records
reviewing quality management

Based on the results of the audit, a detailed project list was developed that further subdivided all compliance issues by size, scope, quality impact, and time of implementation. This was then developed into a project management plan and uploaded into the existing GAP analysis, making it a more proactive and focused document, and giving the pharmacy management team an overall customized assessment and implementation plan.

Turning words into action

The first step in the implementation phase was the establishment of environmental monitoring (E/M) capability within the sterile cleanroom where the compounding of sterile preparations (CSPs) would take place. Environmental monitoring standard operating procedures (SOPs) were also developed, including location-specific, sampling-site maps. The maps clustered sampling points around product critical areas.

Figure 1: Brigham and Womens Hospital sterile products cleanroom microbiological surface testing of TPN laminar flow hood

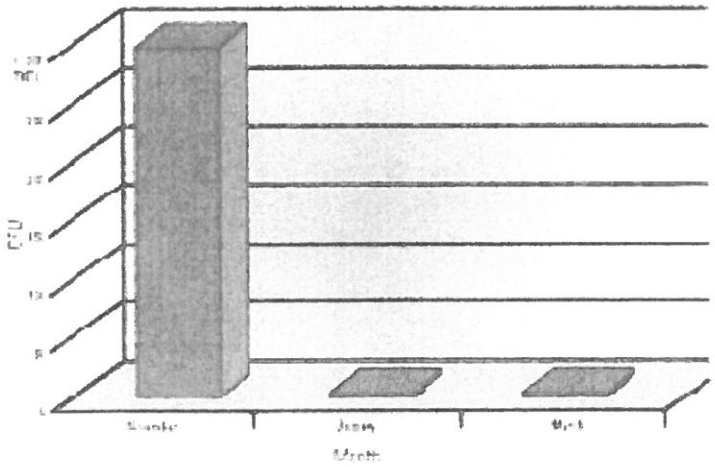


Click here to enlarge image

Microbiological sampling utilized specific media to exhibit both bacterial and fungal contamination, and sampling techniques and frequency were also delineated. Not only did environmental monitoring provide a feedback loop for overall cleanliness and sanitization of the cleanroom, it also provided trending data, which gave BWH pharmacy managers quantifiable performance management tools to help ascertain the quality of the sterile CSP area (see Fig. 1).

One immediate benefit of the environmental monitoring data was the clear demonstration that a stricter gowning policy for CSPs was needed. As a result, in addition to scrubs, booties, bouffants and gloves, gowning was upgraded to sterile, disposable, one-piece cleanroom coveralls. This proved to be a dramatic improvement over the ubiquitous blue scrubs and the new gowning requirements were stipulated in formal quality standard operating procedures.

Figure 2: Brigham and Womens Hospital CSP personnel monitoring garments



Click here to enlarge image

The CSP staff were trained in the new gowning procedures and gowning proficiency was tested using contact plates at multiple gown sites (hands, forearms, chest). Staff members who passed the gowning tests were certified to work in the sterile CSP cleanroom. The change in gowning procedures immediately impacted the viable particle environmental monitoring and a decrease in microbiological colony forming units (CFU) was observed (see Fig. 2).

In compliance with USP <797>, a formal quality unit for the pharmacy operation was established consisting of the associate director of pharmacy and the sterile product manager. The responsibilities of the quality unit include add-mixture review, environmental monitoring, documentation control, personnel training, final drug testing, and quality procedure enforcement. The quality unit has senior management approval and support, and multiple quality management

procedures have been developed for documentation change control, review and approval. The quality unit is responsible for the review and approval of documentation, including all standard operating procedures, add-mixture records, and USP testing results. The quality unit also enforces gowning procedures, cleaning procedures, and environmental monitoring.

Another important element of the compliance program was the requirement that the pharmacy staff undergo USP <797> education and training. On-site training seminars were therefore conducted specific to CSPs and a 24-hour, 7-days-a-week operation. Topics included USP <797> compliance, aseptic processing, cleanroom gowning and environmental monitoring. The seminars are required before compounding activities may begin, and there are periodic updates for new personnel.

A formal cleanroom cleaning and sanitization program was also initiated. Since an outside vendor was used for this service, SOPs were developed for them, which included approved BWH sanitizers, appropriate dilutions, specific contact times for cleaners, application procedures, frequency of sanitizations, and a list of equipment and materials to be sanitized. The validation of the cleaning was conducted at both pre- and post-clean scenarios by environmental monitoring to demonstrate microbial reductions of various areas such as floors, walls, ceiling, laminar flow hoods, and equipment used in preparing sterile preparations. The validation demonstrated a successful cleaning process that adhered to BWH procedures and met acceptance criteria for microbial reduction.

Drug testing of CSPs to strict current USP <71> sterility testing requirements and current USP <85> bacterial endotoxin testing were also initiated. This will be required for CSP in batch sizes greater than 25. Both outside and internal microbiological testing laboratories must also be compliant with GLP/GMP as well as USP <797>. Inhibition/enhancement testing per CSP formulation for USP <85> should be performed initially to validate test results, as well as bacteriostasis and fungistasis validation testing for USP <71> compliance.

Looking ahead, Brigham and Women's Hospital will continue to build on compliance activities. For example, media fill validation testing has been performed on initial fill equipment (i.e., TPN) to demonstrate consistent sterility, and calibration of monitoring devices such as thermometer and chart recorders will be implemented to show traceability to USP standards.

In summary, the implementation of a USP <797> compliance program has improved overall pharmacy compounding quality. The improvements in technique, training, staff education, standard operating procedures, daily sanitization, and environmental monitoring have created a quality program with proactive performance feedback that enables Brigham and Women's Hospital pharmacy to provide meticulous patient care in a fast-pace, high-volume setting.

Fran McAteer, MS, MBA, is vice president of Microbiology Research Associates (Acton, MA), a consulting laboratory for USP <797> compliance. He can be contacted at mra.ma@rcn.com.

William Churchill, MS Hospital Pharmacy, is director of pharmacy services at Brigham and Women's Hospital.

John Fanikos, MBA, is assistant director of pharmacy services at Brigham and Women's Hospital.

Michael Cotugno is the pharmacy manager at Brigham and Women's Hospital.

Caryn Domenici, RPh, is the sterile products room supervisor at Brigham and Women's Hospital.

References

United States Pharmacopeia. USP 29, Chapter 797: Pharmaceutical Compounding-Sterile Preparations. Rockville, MD, 2004.